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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,422	04/16/2007	Robert Hes	0218.094.0002	3688
68153 7590 12/08/2010 GLOBUS MEDICAL, INC. VALLEY FORGE BUSINESS CENTER 2560 GENERAL ARMISTEAD AVENUE AUDUBON, PA 19403				
EXAMINER LAWSON, MATTHEW JAMES				
ART UNIT		PAPER NUMBER		
3775				
MAIL DATE		DELIVERY MODE		
12/08/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/583,422

Applicant(s)

HES ET AL.

Examiner

MATTHEW LAWSON

Art Unit

3775

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-10, 12, 13 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, 12, 13 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30th November 2010 has been entered.

Response to Arguments

Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-10, 12-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrespa (US 5,593,410) in view of Bono et al. (US 6,129,730).

Regarding claims 1-3, 6-10, 12-13, and 17 Vrespa discloses a bone screw (figure 1) having a lead portion (24, figure 8) and a tail portion (23, figure 8), and an intermediate

transition portion (22, figure 8), each of the lead portion and the tail portion comprising a root (32-24, figure 1) and a thread (26/28, figure 1), having a thread lead (figure 1) formed on the root, the thread on the lead portion having an approximately constant diameter along a significant portion of its length and tail portion having an approximately constant diameter along a significant portion of its length (figure 1), in which the diameter of the thread on the tail portion is greater than that of the thread on the lead portion (figure 1), and in which the thread lead of the thread on the lead portion is equal to the thread lead of the thread on the tail portion (figure 1), wherein the intermediate transition portion is configured between the threads of the lead portion and the tail portion, and is provided with a diameter that decreases gradually between the thread of the lead portion and the thread of the tail portion (figure 8), wherein the tail portion is provided with a socket end (16, figure 1), wherein the socket end of the tail portion is adapted to be, *i.e. capable*, flush with the surface of the bone or under the surface of the bone after the bone screw is fully inserted, and the thread on the lead portion of the screw is a multi-start thread (column 12, lines 55-58) in which the number of starts of the thread on the lead portion is equal to the ratio of the thread pitch of the thread on the tail portion to the thread pitch of the thread on the lead portion (column 12, lines 63-67), and the thread on the tail portion of the screw is a single-start thread (column 12, line 43), in which the diameter of the root of the tail portion is greater than the diameter of the root of the lead portion (figure 1), and the diameter of the root of the tail portion is greater than the diameter of the root of the lead portion, and has a bore (30, figure 1,

and 74, figure 4-5) extending through it along its length.

Vrespa et al. fail to expressly disclose the lead portion of the screw being a double-start thread and the tail portion of the screw being a single start thread and the pitch of the thread on the tail portion is equal to twice the thread pitch of the thread on the lead portion. Rather, Vrespa et al. teach that the threading on the lead portion of the screw is a multiple of the threading on the tail portion of the screw and having a respective difference in pitch between the respective portions of the screw equal to that multiple (see abstract, column 7, lines 54-67, column 12, lines 63-67).

Bono et al. teach the use of multi-lead/threaded lead portion and a tail portion of the screw having a single start threading. Bono in particular expressly teaches the use of double, triple, quadruple, or quintuple along with "others" (column 3, lines 61-67, column 4, lines 1-3) to provide a screw with the most desirable pull-out values inhibiting pull-out of the screw from cancellous bone (column 3, lines 61-67, column 4, lines 1-3). As such both Bono et al. and Vrespa both use a multi-start threading on the lead portion to remedy the same issue of obtaining the best purchase within the cancellous bone thereby inhibiting pull-out of the screw.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the lead screw portion of Vrespa to have a dual start threading instead of triple start threading as taught by Bono et al. to provide the screw with the most desirable pull-out values to inhibit pulling out of the screw from the cancellous bone region.

Regarding claims 6-7, Vrespa in view of Bono disclose the claimed invention except for the ratio of the diameter of the thread on the tail portion to that of the diameter of the thread on the lead portion is at least about 1.2, preferably at least about 1.5, and is not more than about 2.3, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the diameter of the thread on the tail portion to that of the diameter of the thread on the lead portion to be at least about 1.2, preferably at least about 1.5, and is not more than about 2.3, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 9-10, Vrespa in view of Bono disclose the claimed invention except for the ratio of the diameter of the root on the tail portion to that of the diameter of the root on the lead portion is at least about 1.2, preferably at least about 1.4, and is not more than about 2.3, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the diameter of the root on the tail portion to that of the diameter of the root on the lead portion to be at least about 1.2, preferably at least about 1.4, and is not more than about 2.3, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 12-13, Vrespa in view of Bono disclose the claimed invention except for the ratio of the diameter of the thread aspect on the tail portion to that of the

thread aspect ratio on the lead portion is at least about 1.2, preferably at least about 1.35, and is not more than about 2.2, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread aspect ratio of the tail portion with respect to the lead portion to be at least about 1.2, preferably at least about 1.35, and is not more than about 2.2, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 17, Vrespa in view of Bono discloses the claimed invention except for the root diameter of the lead portion is 4.5 mm and a root diameter of the tail portion is 6.5 mm.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the root diameter of the lead portion is 4.5 mm and a root diameter of the tail portion is 6.5 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vrespa (US 5,593,410) in view of Bono et al. (US 6,129,730) in further view of Frigg et al. (US 5,180,382).

Vrespa in view of Bono disclose the claimed invention except for the threading on the tail portion of the screw being a continuation of the one of the threads on the lead portion.

Frigg et al. disclose the threading on the leading portion (7, figure 1) with

threading and a tail portion (6, figure 1) with threading which is a continuation of the threading on the lead portion (figure 1) to permit continuous threading of the screw allowing for non-stop engagement within the bone/insertion body.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the device of Vrespa in view of Bono to having continuous threading between the leading and trailing portions of the screw to permit continuous threading of the screw allowing for non-stop engagement within the bone/insertion body as taught by Frigg et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW LAWSON whose telephone number is (571)270-7375. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. L./
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775